Exhibit D

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MASTER FILE NUMBER 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
PAMELA BAILEY AND HOUSTON BAILEY, Plaintiffs, vs. ETHICON, INC., et al., Defendants.	CASE NUMBER 2:12-CV-01700

DEPOSITION OF
JOYE LOWMAN, M.D.

June 24, 2016
12:17 p.m.

600 Peachtree Street, NE
Suite 5300
Atlanta, Georgia 30308

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JOYE LOWMAN, M.D.,
having been produced and first duly sworn as a witness, testified as follows:

EXAMINATION

BY MR. THOMPSON:

Q Dr. Lowman, we're now going to move to a deposition where I question you about Miss Bailey. Now, I've actually used her as an example all the way through the sort of general questions, the general opinions that you had, so some of this is going to sound a little bit like plowing the same ground, but there is -- rather than be very sophisticated about it, I think we'll actually move more quickly if we just plow the same ground, so I'm going to go forward as we go.

Doctor, when were you communicated Miss Bailey's records? When were they sent to you?

A I don't remember exactly.

Q Is that reflected on the invoice sheet? Would that be of help to you?

A Unfortunately, no.

Q Is it recently? Is it --

A What is this? June. I've been working on wave two, I believe since January. Does that -- or

February? I'm not sure.

Q You know, it's not that important.

A Good.

Q But what I mean to say is that you have not been -- you were never involved in the care and treatment of Miss Bailey; is that right?

A That's right.

Q And you have not performed an independent medical examination on Miss Bailey, have you?

A I have not.

MR. RUMANEK: And I'll just note for the record that there was an agreement amongst counsel that that could be deferred until the trial.

BY MR. THOMPSON:

Q Is an IME an important part of your opinion, or are you prepared -- I mean, you've written a pretty substantial opinion. Do you feel like you have enough information to state opinions with finality?

A According to the information that I currently have, yes. If something develops differently, if someone else does an IME and finds something that is inconsistent with what I currently

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have, then that might change.
Q Now, Miss Bailey had a TVT implanted in 2001; correct?
A Let me check. I believe that's correct, yes.
Q And I'm going to ask you to go to the -- just to have it in front of you, the Windy Hill records.
A Okay. That's this; right?
Q Yes. Do the records reflect the reason for her TVT?
A They do.
Q And what was the reason?
A Stress incontinence.
Q Were there any other presenting symptoms that Miss Bailey had that you would find remarkable?
MR. RUMANEK: Objection to form. Do you want her to look through all the records?
THE WITNESS: Not that I'm aware of.
BY MR. THOMPSON:
Q Now, Miss Bailey at the time of this implantation was heavy; is that right?
A That's correct.
Q I believe that there is a record in here

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that says she was five-four and about 180-something pounds. Does that sound right?
MR. RUMANEK: Objection to form.
THE WITNESS: That looks right.
BY MR. THOMPSON:
Q Let's just find it rather than me trying to remember it.
MR. RUMANEK: Do you have that?
THE WITNESS: On page 5.
BY MR. THOMPSON:
Q Look to page 11.
A On page 5 as well, the --
Q Right. There we go. Five -- oh, I was giving her an extra inch. Five-three, 180 pounds. Okay. Now, there is no contraindication for a TVT for weight, is there?
A There is not.
Q Does the record reflect whether or not she's a smoker? If I look up at the top, it says, "Past medical HX."
MR. RUMANEK: What page are you on?
MR. THOMPSON: I am still on page 5.
THE WITNESS: Yeah. I'm not sure what that -- six to seven packs per day sounds

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extremely heavy. I'm not -- that doesn't -- that might be pads per day.
BY MR. THOMPSON:
Q Where are we at?
A You're looking at the history of present illness?
Q Yes. I was actually looking at Number 14, tobacco. It wasn't checked.
A Oh, Number 14. Oh, okay. Yes. So it doesn't look like that was checked.
Q So this is -- and I think we're probably in agreement that it is six or seven pads per day.
A Right.
Q That would be somebody who has -- is there any characterization for the degree of incontinence that that would represent, or that's just a --
A Nothing objective, but subjectively that's significant.
Q Now, she was 33 years old at the time; is that right?
A That's correct.
Q That's kind of young to be getting a mid-urethral sling --

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MR. RUMANEK: Objection to form.
BY MR. THOMPSON:
Q -- isn't it? Or is it not?
A No.
Q That's not remarkable of itself?
A No.
Q But it would be something that would fit into if -- there was some question as to whether or not her problems might be caused by, say, vaginal atrophy. Her age would militate against that, wouldn't it?
A Yes.
Q Is there anything in her record that you would see that would make her not a candidate for a TVT?
A No.
Q In your opinion was she a prior -- was a diagnosis and a prescription for a TVT, an appropriate medical decision?
A Yes.
Q If I go all the way to the last two pages of this, 39 and 40, do you see that?
A I do.
Q And the thing we have to do, as we look

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at this, we have to keep reminding ourselves that this is in 2001; right?
A Okay.
Q Now, you were in medical school in 2001; right?
A I -- I was, yes.
Q So you were not installing or thinking about TVTs, per se, in 2001; correct?
MR. RUMANEK: Objection to form.
THE WITNESS: Correct.
BY MR. THOMPSON:
Q And unfortunately for me, in 2001 I was probably already old, but Eric here was probably like four years old. But anyway, we have to keep reminding ourselves that we're dealing with the medical knowledge, medical decisions as existed in 2001; correct?
A Correct.
Q If I look at this informed consent, this is a preprinted form that has no additional material risk placed in it.
MR. RUMANEK: Objection to form.
BY MR. THOMPSON:
Q Isn't that right?

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A It looks that way, uh-huh.
Q Now, if you were doing a procedure for a TVT today, does Kaiser Permanente have a preprinted TVT informed consent form?
A They don't.
Q Do you have a form in which you fill out the elements of discussion that you had with the patient and the risks that you communicated to the patient?
MR. RUMANEK: Objection to form.
THE WITNESS: We use preprinted forms. They're just not from Kaiser, so --
BY MR. THOMPSON:
Q Yes.
A -- most of the hospitals do have preprinted consent forms.
Q And the preprinted consent form is for a particular type of procedure; is that right?
A It depends on the hospital.
Q Well, how about the hospital where you perform your TVT?
A Well, I operate at four hospitals.
Q Oh, okay.
A At Northside they have specific forms for

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specific procedures. At Piedmont they don't. At Gwinnett -- I can't remember. I think that they do.
Q Do you do any TVT surgeries as an office procedure?
A No.
Q And in any event, looking at this consent form, this consent form does not have any particular or discrete recitation of risks unique to vaginal tape procedure, does it?
A What do you mean by that?
Q I mean, does it talk about potential for erosion or exposure?
MR. RUMANEK: In the form?
MR. THOMPSON: Within the form, right.
THE WITNESS: It does not.
BY MR. THOMPSON:
Q And does it talk about the risk for, I don't know, voiding disorders --
A That's not --
Q -- within the form?
A That's not listed, no.
Q Dyspareunia or painful sex?
A That's not listed either.
Q How about pelvic pain?

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A That's not listed on the preprinted form.
Q And I don't mean to go through everything exhaustively, but simply to say that in 2001 this form did not contain a lengthy list of specific adverse events that could be suffered as a result of a TVT implantation --
MR. RUMANEK: Objection to form.
BY MR. THOMPSON:
Q -- does it?
A It doesn't, but it does allow for that discussion because it says, "In addition to these material risks there may be other possible risks involved in this procedure, including but not limited to," and there is nothing written there, and then it says, "I understand and acknowledge that by signing this form I've been fully informed to my satisfaction in general terms of the following: The diagnosis, the nature and purpose of the procedure, the material risks of the procedure."
So it's specific to the procedure.
MR. RUMANEK: Just slow down a little bit just --
THE WITNESS: Sorry.
MR. RUMANEK: -- so he can keep up with

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you.
THE WITNESS: "Likelihood of success of the procedure, alternatives." So it gives, you know, grounds for that more specific discussion, but those preprinted -- are those things specifically preprinted on this form? No.
BY MR. THOMPSON:
Q Now, did Dr. Perlow sign this form?
A I don't see his signature here.
Q Let's go back to the beginning and just find his -- I guess, let's go to page 7, which is his operative note.
A Okay.
Q Is there any discussion in there that he had a discussion about risks or complications? Within the operative note?
A No.
Q Let's look through this together and just see if we can find one, because that's what I am doing, so you help me out.
A A discussion of risks to --
Q Yes, ma'am.
A Those are all -- these look to be all

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hospital notes, so I wouldn't expect them to document a discussion sort of after the fact.
Q Oh, okay. Okay. So what we can say is that we don't see any, but that doesn't mean they don't exist?
A Right.
Q Let's don't spend any more time on that because I did want to talk about the operative note itself. Do you have any information about how Dr. Perlow learned to do a TVT procedure?
A I don't.
Q Do you know when the TVT was first available in America?
A In the late 1990s.
Q Now, in your opinion Number 1 in your report you fault not the TVT device, but you say that Miss Bailey's problem was caused by overtensioning the TVT at implantation; is that right?
A That's correct.
Q And the key word that you have used, and you quoted it several times here at the bottom of page 7 -- no, that's not right.
MR. RUMANEK: I'm just going to object to the extent you're characterizing any words that

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she used as being key, that phrase, whatever you used.
BY MR. THOMPSON:
Q Well, all right. Then let me withdraw that since what I am looking at is the last paragraph on page 7, which is page 1 of 2 of the operative note.
A Okay.
Q Now, you quote in your report, the section of this report where it says that he pulled -- vaginal tape was pulled taut --
A Uh-huh.
Q -- correct?
A Correct.
Q Now, the entire sentence there is, "Vaginal tape was pulled taut so that it would suspend the urethra, period. A Metzenbaum scissors was used as a spacer."
Correct?
A That's correct.
Q Now, from that, you -- is there anything else that goes into your opinion that this device -- that Miss Bailey's problems were caused by overtensioning?
A Yes. He also remarks that she was asked

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to cough and there was no leakage noted. When the sling is optimally placed, there is a little bit of leakage noted, so that's an indication too that it was too tight.
Q If it was too -- if there was no leakage noted, would she have had voiding problems or would she have had trouble voiding postoperatively?
MR. RUMANEK: Objection to form.
THE WITNESS: You can't necessarily tell just from the lack of leakage with cough or Crede maneuver or however you're testing the sling. But what he describes in addition to that notation that she didn't have any leakage -- which we usually want a drop or two of leakage. In addition to her -- the urodynamic testing that she had that, you know, demonstrated that she had obstruction, I mean, those things together show that she had obstructive voiding.
BY MR. THOMPSON:
Q When was the urodynamic testing?
A Whenever she saw Dr. Adam.
Q Now, that was in 2005; right?
A Let's see. Yes.

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Q And she was complaining of having some retention or trouble voiding when she presented with Dr. Adam; is that right?
A Uh-huh, yes.
Q Well, I guess what I am more interested in is if I look at the immediate aftermath of the implantation on 4/19 of 2001, the nurse's notes and the recovery process notes, that she has -- urine flow has returned, doesn't it?
MR. RUMANEK: Do you want to reference the specific --
THE WITNESS: What page?
BY MR. THOMPSON:
Q Let's look at it. I guess page 33 is a good page to look at. If I look on 4/20/01, see down that right side? I'm not sure if this is a nurse's note or what exactly it is, but it looks like a periodic input by a professional. Do you see what I am looking at?
A I think so. These handwritten notes on this side?
Q Yes. 4/20 of 2001, "Resting quietly at this time; will" -- I'm not sure -- something "as needed"?

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A "Assist."
Q "Assist as needed. Vaginal packing removed. Foley" something.
A "Foley removed." She was only able to void 50 CCs.
Q "Patient able to void 50 CCs; will try again." Something "became nauseated."
A Right.
Q Something, something. Okay?
A So that's not a normal void.
Q But it's actually part of Ethicon's instructions that sometimes people can't void for 48 hours and you have to send them home on a catheter. I mean, isn't that within the range of outcomes that are expected?
MR. RUMANEK: Objection to form to the extent you characterized that as Ethicon's instructions.
THE WITNESS: It's well known that patients can have voiding dysfunction right after surgery. It's also well known that they can have voiding dysfunction from the sling being too tight, so yes.
BY MR. THOMPSON:

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Q So it could be one or the other?
A It could be.
Q Or it could be something else?
A Well, we know she's got voiding dysfunction.
Q Well, except what we do know is that she eventually went home and made no more complaints for a while; isn't that right?
A That doesn't mean she doesn't have voiding dysfunction, but she did go home, yes.
Q I have only one of these. I'm sorry. How about let's go and make this a copy. Here again, it's all -- I'm talking while asking you --
(Discussion ensued off the record.)
(Plaintiffs' Exhibit Number P-1 was marked for identification.)
BY MR. THOMPSON:
Q Let me hand you this. This is a document that's actually entitled, "Surgeon's Resource Monograph: A Report of the 2000 Summit Meeting, 17-Surgeon Panel Representing More Than 1200 Cases," written by Gynecare, and I'm going to hand that to you --
A Okay.

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Q -- since it's the only one I have. Now, have you seen that before?
A I have.
Q If I look back to the section on -- and here again I've helped you out a little bit by putting the little yellow stickies on it.
A Okay.
Q If I look back to the installation portion where they discuss using an instrument between the urethra and the tape, do you see that?
A That, I do.
Q And if I turn to the next page, I'm not sure why I have marked the next page, but there is something that's obviously very important to me on the next page as well.
MR. RUMANEK: Do you want to hand it back? Hand it back to you?
BY MR. THOMPSON:
Q Oh, here. It'll be on the next page after that. It says, "Patient cannot void."
Do you see that?
A Okay.
Q Doctor, by putting the instrument between the urethra and the TVT mesh, Dr. Perlow was following

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or complying with the instructions that are included in the Ethicon monograph, is he not?
MR. RUMANEK: Objection to form.
THE WITNESS: No.
BY MR. THOMPSON:
Q And in what way is it your view that he is deviating?
A That's not the only part of what they're instructing there. They say, "To prevent overcorrection, a blunt instrument is placed between the tape and the urethra, remembering looser is better than tighter."
So part of it is having a spacer, but you also have to be cognizant of the amount of tension that you are applying to the sling as you remove the sheath from the sling. So he did place the spacer, but he pulled the sling too tight. He pulled it taut is what he said, and what they're saying is looser is better than tighter.
And then on the other side, when you are talking about the patient cannot void, they say, "Ideally prevention of this complication is the goal. This is determined in the OR by ensuring that the Gynecare TVT mesh is positioned loosely, without

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tension."
Q And you're faulting him because you're saying it was too tight --
MR. RUMANEK: Same objection.
BY MR. THOMPSON:
Q -- and -- yeah, go ahead.
MR. RUMANEK: No. Finish the question.
BY MR. THOMPSON:
Q You're faulting him because you're saying it was too tight, and that means that it needed to be loosened; isn't that right?
MR. RUMANEK: Objection to the form of the question to the extent you're characterizing her testimony as faulting him.
THE WITNESS: No. What I am saying is, he should have placed it without tension. Not necessarily dictating what he should have done after he had --
BY MR. THOMPSON:
Q Yeah.
A -- placed the sling, but during the placement he should have ensured that it was placed loosely as opposed to trying to pull it taut.
Q Now, if he pulled it too taut -- well,

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let me strike that. If it had too much tension, Gynecare advised him to do what to correct it?
MR. RUMANEK: Objection to form.
THE WITNESS: Well, they give options, so they said that within the first five to ten days outlet obstruction can be relieved by opening the vaginal incision, grasping the tape, and pulling it downward. After ten days it's not possible to pull it downward. At that point the outlet obstruction can be relieved by making a vaginal incision under local anesthesia and dividing the tape in the midline.
BY MR. THOMPSON:
Q Now, she was voiding within 24 hours of the procedure; is that right?
A I'm not sure.
Q Well, we've looked at this note in the recovery room.
A Yes. Fifty CCs is not a normal void. I'm not sure if she required catheterization or not.
Q Well, I guess that's my question. Did she require catheterization, according to the records you've reviewed?

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A I don't remember. I didn't have that -- that part of her record.
Q Assuming that she did not have symptoms for a period of time after the procedure, is that -- well, if we make that assumption, would that impact your view that the TVT was overtensioned?
MR. RUMANEK: Objection to form.
THE WITNESS: No.
BY MR. THOMPSON:
Q You'd earlier -- and let me make sure I understand and can reconcile it in my own mind. You'd earlier said that you have, on occasion, overtensioned a TVT device; is that right?
A That's correct.
Q And on those occasions you've waited 12 weeks because that is the optimum time to effect a proper adjustment --
MR. RUMANEK: Objection --
BY MR. THOMPSON:
Q -- is that right?
MR. RUMANEK: Objection to form.
THE WITNESS: Yes. But let me qualify that by, I don't see patients in complete retention, so -- complete retention is where

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they're not voiding at all or maybe voiding 20 or 30 CCs with residuals of 300, 400, et cetera.

It may behoove you to adjust that sling sooner and possibly to consider repeating the sling if there is -- voiding dysfunction is that severe. So I usually see mild voiding dysfunction -- the patient is not, you know, suffering with a catheter and that kind of thing for three months -- and so it's more reasonable to wait three months in that situation, and that's what I customarily do.

BY MR. THOMPSON:

Q I see. Your procedure, based on your experience and expertise and based on the evidence, differs from the advice that Gynemesh was giving to surgeons in 2000; is that right?

MR. RUMANEK: Objection to form.

THE WITNESS: What I currently do is different than what is listed here, yes.

BY MR. THOMPSON:

Q Have you read Miss Bailey's deposition?

A I did.

Q And I think Dr. Perlow gave a deposition.

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Did you read that?

A I did.

Q Let's go forward to 2005. What I want to do, I want to go ahead and mark this as an exhibit so we have it. Since it's my only copy, I'm going to go ahead and mark it now. This is a -- well, let's -- let me be --

MR. RUMANEK: Do you want to mark the copy -- is that Windy Hill?

MR. THOMPSON: Yes.

MR. RUMANEK: Do you want to mark the copy that I gave her so you can keep your copy?

MR. THOMPSON: Is that okay with you?

MR. RUMANEK: Yes.

MR. THOMPSON: Okay. That would be super.

MR. RUMANEK: I aim to please.

MR. THOMPSON: You what?

MR. RUMANEK: I aim to please. Full service here.

(Plaintiffs' Exhibit Number P-2 was marked for identification.)

BY MR. THOMPSON:

Q Let me just identify it. Just for the record, what I marked as Plaintiffs' Exhibit Number 2 is a document consisting of 40 pages, which is the result of a search request of Windy Hill Hospital, and it's Bates numbered MDR0001 through 00040, and this is the document that we've been making some reference to over the last few minutes of deposition. Right there. All right.

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Doctor, let's go to your report, and let's see -- and now I'm going to actually go back a little bit from opinion Number 1. I'm going to go back to your chronology and say, when is the next time that you have reviewed records that show healthcare sought by Miss Bailey?

MR. RUMANEK: Let me just make sure. Are you asking after the implant?

MR. THOMPSON: Yes, after the implant.

MR. RUMANEK: When was the next time that she sought healthcare, or what's reflected in the chronology? Those may be different.

MR. THOMPSON: Well, let me ask it this way.

BY MR. THOMPSON:

Q Doctor, you've included a chronology for Miss Bailey starting on page 18 --

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A That's correct, yes.

Q -- of your report? In doing this chronology have you included the healthcare encounters that you believe are relevant and material to your opinion of Miss Bailey?

MR. RUMANEK: I object to the extent she may differ in terms of what is relevant as you characterized it.

THE WITNESS: I included all of the encounters that were in the sort of key medical records that I was given. I'm not sure if there are other medical records that are relevant that I didn't see, but in terms of what I thought was important, that's what I have included here.

BY MR. THOMPSON:

Q Well, actually let me do it in the form of leading questions and just get through this really quickly.

A Okay.

Q You recite that on 5/28 of '02 Miss Bailey was seen by Dr. Reker for complaints of obesity; correct?

A That's correct.

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Q Now, have you reviewed any documents between her release from the hospital on April 20th, 2001, and May 28, 2002?
A I may have. I don't remember specifically.
Q There is nothing in your report that indicates any complaint with regard to voiding dysfunction by Miss Bailey between 4/19 of '01 -- I'm sorry; 4/20/2001 and 5/28/02 --
MR. RUMANEK: Object --
BY MR. THOMPSON:
Q -- is that right?
MR. RUMANEK: Objection to form to the extent that that mischaracterizes Miss Bailey's testimony at deposition.
THE WITNESS: That's correct.
BY MR. THOMPSON:
Q Well, I mean, you've read her deposition where she does talk about having trouble with voiding; correct?
A I have.
Q But what I am asking very specifically is, is there any notation in a medical record that you have reviewed that shows a complaint of voiding

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dysfunction between 4/20/01 and 5/28 of '02?
A I don't believe so. I think if I'd seen that, I would have noted it.
Q And so on May 28, '02, why did she go see Dr. Reker? Or Reker.
A It's --
MR. RUMANEK: That record there. You can go to the record if you need to.
THE WITNESS: According to my report, she was complaining of obesity. She was complaining of difficulty exercising because of foot, knee, and back pain. She was complaining of incontinence despite having the TVT done. She was requesting to be referred for gastric bypass surgery.
BY MR. THOMPSON:
Q I guess we do need to have a look at that record because the question I have for you is, was it incontinence coupled with not being able to pee, or was it incontinence?
A She did not complain of difficulty urinating.
Q So let's go forward to May 1, '03. Your report notes that she was seen by Dr. Osterloh for

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follow-up on obesity.
A Okay.
Q Let's have a quick look at that and see if she made any complaints with regard to voiding or urination at that time.
A She did not.
Q And then on October the 13th of 2003 she did complain of an increased urination; is that right?
A Urinary frequency, yes.
Q And she at least -- either she or the doctor ascribed it to a side effect of hypertension and maybe even some sort of anxiety or tense; is that right?
MR. RUMANEK: Objection to form.
THE WITNESS: Where are you getting that from?
BY MR. THOMPSON:
Q I'm getting that --
A I'm looking at the assessment.
Q Yeah. I'm actually reading that off your report.
A From this -- what date is this?
Q This is October --
A Maybe I'm looking at a different --

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Q -- October 13th --
A Oh --
Q -- 2003.
A -- I'm looking at the wrong thing here. Where is October 13th? October 13th, 2003. Okay. Could you ask the question again?
Q Just that she has increased urination, but somebody ascribes it to a side effect of hypertension and anxiety.
A Uh-huh. Let me see what I wrote here. Oh, right. She says that she has been compliant with the Diovan and her only side effect has been increased urination, so she complained of that.
Q And so she doesn't -- and she's not -- on 10/13 of '03 she's not looking to and blaming the TVT as any cause of her present condition, is she?
MR. RUMANEK: Objection to form.
THE WITNESS: She isn't --
MR. RUMANEK: Based on the medical record?
MR. THOMPSON: Based on the medical record.
THE WITNESS: Based on the medical record, no.

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BY MR. THOMPSON:
Q And Eric is exactly right. I mean to say, does the medical record reflect that she has complained that the TVT is causing any part of her problem?
A She does not.
Q You then look to 12/3 of 2004. She was seen by Dr. Sward.
A Uh-huh, yes.
Q And he diagnosed her with a UTI and referred her to a urologist for further evaluation; is that right?
A That's correct.
Q Then on 12/10 of 2004 Miss Bailey was seen by a urologist, Dr. Schrum, who had a -- he reported that Miss Bailey had complex urinary incontinence at baseline and her incontinence has worsened after TVT and collagen injections; right?
A That's correct.
Q Then he referred her to Emory, and that's where we pick up Dr. Adams -- I am sorry; Adam -- is that right?
A That's correct.
Q Now, this here is some -- now, did

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Dr. Adam note that there was a mesh exposure?
A He did.
Q And did he record her -- a history that she gave?
A He did.
Q And what was that history?
A Do you want me to just --
MR. RUMANEK: Look at it.
BY MR. THOMPSON:
Q Yes, ma'am. That would be great.
A "This is a 37-year-old P1 001 with a history of anterior compartment prolapse, status post previous surgery that the patient describes as a vaginal bladder tack with a mesh sling in 1999 followed by a collagen injection in 2000. She was referred here by Dr. Forrest Schrum for urinary incontinence. She reports leaking with standing and bending to sit down.
She does not particularly notice leaking with coughing or sneezing. She states that she leaks usually without warning. She denies any significant urgency. However, she does report frequent urination and also has a problem with incomplete emptying of the bladder and difficulty initiating her voids as well as

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a slow stream. She reports nocturia two to three times per night.
She wears pads for most of the day. She denies any pressure symptoms, but she does report difficulty during intercourse. She said her partner can feel something inside the vagina. She denies any excessive consumption of caffeine or coffee. She reports normal bowel movements and denies any constipation or incontinence of stool. She reports no improvement after her first surgery. After her collagen injection in 2000, she did report some improvement for only two months.
She previously tried Ditropan and Detrol, and she states these medications do not help her. More recently the doctor who saw her thought that the mesh from her previous surgery may have caused some erosion, and she was told that she had blood present in the urine. She denies any dysuria currently and denies any abnormal vaginal bleeding."
Q Now, did he formulate a plan of action or a treatment plan?
A Yes, he did. He did a physical exam, and then his assessment and plan was, "37-year-old female status post anterior prolapse surgery with vaginal

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erosion of mesh on exam today. Also with a history of hematuria, dyspareunia, stress incontinence versus overactive bladder. Possible sensory abnormality with feeling of fullness and small capacity. No evidence of overflow incontinence."
MR. RUMANEK: Just, there is another paragraph. I don't know if you want her to read it or not.
THE WITNESS: "She was instructed to obtain her operative reports from her prior surgeries. She was given a uro-log and hat to complete. She was scheduled for urodynamics. She made need a future cystourethroscopy and exam under anesthesia to rule out urethral erosion. She is to follow up in the office after her urodynamics are completed."
BY MR. THOMPSON:
Q Now, if she reported that her mesh surgery was in 1999 and she had collagen -- maybe I have that backwards. Mesh in 1999 and collagen in 2000, can we say from the medical records that you have reviewed, that Miss Bailey is not the best reporter of her medical history or that at least in some parts her memory is at odds with the medical

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records?
MR. RUMANEK: Objection to form to the extent that you're asking Dr. Lowman to characterize something beyond what's reflected in that particular record.
THE WITNESS: In terms of the dates, she was incorrect with the dates.
BY MR. THOMPSON:
Q And did Dr. Adam perform a partial excision of the TVT?
A He did.
Q And the purpose for his surgery was what?
A To relieve her obstruction.
Q And did that succeed?
A I believe it was his opinion that it did, yes.
Q Do you know how much mesh was removed?
A I believe we -- I commented about that. She should have a path report here. I will just look at my report. I believe it was three centimeters.
Q Here is -- what I should do is refer you to this operative report. I'm sorry. And for some reason this is not a Bates-numbered form.
A This is the op report. Yes,

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three-centimeter segment.
THE REPORTER: Sorry, Doctor. Could you keep your voice up?
THE WITNESS: I'm sorry. I'm sort of talking to myself. The three --
MR. RUMANEK: Hold on just a second. Let's go off the record one second.
(Discussion ensued off the record.)
MR. RUMANEK: We can go back on the record.
BY MR. THOMPSON:
Q Tell me the Bates number that you're looking at for the op report.
MR. RUMANEK: It's Bailey P, underscore, PSR, underscore, 00140 through 142.
MR. THOMPSON: All right. I have a giant stack. Let's just take you up on your offer.
MR. RUMANEK: Do you need that, or --
BY MR. THOMPSON:
Q Well, just if you have it in front of you, let me just ask you some questions about it.
A Okay.
Q If I look at the document that's entitled, "Emory Healthcare, Bailey Pamela, admit

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date, 6/20 of 2005" --
A Okay.
Q Yeah. All right? I have, "The risks and benefits of the procedure were discussed at length with the patient by Dr. Adam on May 19th, 2005, and again by myself at her preoperative visit on June 15. She states she has no questions."
MR. RUMANEK: Where are you reading from?
THE WITNESS: He's reading from the top.
MR. RUMANEK: Oh, okay. From the top. Oh, okay.
BY MR. THOMPSON:
Q So that's -- now, if I go to the operative record itself, which is page 12 and page 13 of the operative report, it looks as though you're exactly right. It looks like he removed approximately a three-centimeter segment of mesh. Is that correct? On page 13?
A Yes.
Q And when he opened her up, did he find what he calls eroding through the vaginal mucosa?
MR. RUMANEK: Objection to form.
BY MR. THOMPSON:
Q Look to the first full paragraph on

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page 13.
A The mesh, which was tinting up the urethra was --
THE REPORTER: Sorry, Doctor.
THE WITNESS: I'm just reading to myself. I'll read it out.
MR. RUMANEK: Out loud. Just read it to yourself.
THE WITNESS: Okay.
MR. RUMANEK: Is the question, did he observe erosion after he opened her up? Is that what you are asking?
MR. THOMPSON: That was my question, yes.
THE WITNESS: I don't see him documenting that. Oh, yes, I do. Yes, he did.
BY MR. THOMPSON:
Q And he did not note -- and we in the mesh field would call that an exposure. Is that right?
A That's correct.
Q And he did not note an erosion into the urethra; is that right?
A That's correct.
Q What does tinting mean?
A That it is elevating the urethra as

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opposed to just lying flat under the urethra.
Q I see. Is that a function of tension?
A Yes.
Q Doctor, this is four years postsurgery; correct?
A That's correct.
Q Is it within the range of potential that what was noted by Dr. Adam was a contraction of the TVT from the time of implanting until the time that he excised it?
A That would be unlikely.
Q Is it within the list of possibilities?
A If I have to answer yes or no, I'd have to say no. I'm not aware of any evidence that mesh that is not attached or anchored, contracts.
Q If the form by which the mesh is innervated or ingrown results in a shrinkage of the footprint of the mesh, is that a possibility? That the tinting could have been caused by the contraction of the mesh during the ingrowing process?
A No.
Q When he removed the mesh, what did he leave?
MR. RUMANEK: Objection to form.

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THE WITNESS: He describes that once the mesh was freed, it was excised bilaterally at its entrance into the pelvic diaphragm, so he left the abdominal portion of the sling.
BY MR. THOMPSON:
Q The abdominal portion, and here again --
A The retropubic portion.
Q Here again, the risk that you always -- you don't run this risk, but I always run this risk is disclosing how little I understand about anatomy. Did he leave both sides?
A Yes.
Q Doctor, do you have any complaints or in reviewing this record do you have any criticisms of Dr. Adam, of his procedure or technique?
A No.
Q With regard to his decision to excise the portion of the mesh, do you have any criticism of that medical decision?
A No.
Q Do you think that was the right decision?
A I think it was acceptable, yes.
Q Now, Doctor, if I go to July 14 of 2005, which is a four-week postop check -- do you see that?

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A I do.
Q Do you see where she reports she feels like she has a full bladder and voided only 63 CCs? Do you see that?
A Yes.
Q And she reports having the urgency to urinate even after voiding?
A Yes.
Q Now, if we go way back to April 20, 2001, if you remember, she was voiding 50 CCs at that time. Would the removal of that section of the TVT -- would that removal have relieved the pressure on her and allowed her to void more freely?
MR. RUMANEK: Objection to form.
THE WITNESS: Yes.
BY MR. THOMPSON:
Q And why do you think it didn't?
A It did. She voided 63 CCs with a postvoid residual of 10 CCs, so she emptied her bladder volume normally. The abnormal thing is that she still feels like she needs to go, which is just a sign of overactive bladder.
Q I see. Do you think she's had overactive bladder all along?

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A She may have had overactive bladder preoperatively from the TVT is what you are asking?
Q Well, from the TVT, unrelated to the TVT. Just, did she have overactive bladder?
A It wasn't documented. I mean, her -- the indication for her TVT was stress incontinence. It wasn't mixed incontinence. When she saw -- I forget who it is now that said that she had complex incontinence --
Q Yeah.
A -- that's a suggestion that maybe she had mixed incontinence, but certainly her symptoms seemed to worsen after the TVT in terms of the overactive bladder symptoms.
Q Now, Doctor, at that visit on 7/14 of '05, whatever was said back and forth, she was prescribed a follow-up for three months later. Do you see that?
A Yes. She was prescribed medication for overactive bladder and then asked to follow up in three months.
Q So whatever was said, does the three-month follow-up indicate that the medical professionals who were following her, considered her

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to be nonemergent?
MR. RUMANEK: Objection to form.
THE WITNESS: Yes.
BY MR. THOMPSON:
Q That they were willing to -- they saw her as someone who could, in essence, resume a normal routine?
MR. RUMANEK: Objection to form.
THE WITNESS: Yes.
BY MR. THOMPSON:
Q Now, I see there is a visit for low back pain on August 30th, 2005.
A Yes.
Q And at that point -- she doesn't complain of incontinence at that point; is that right?
A That's correct.
Q Now, the next record that any of us have seen is on June 28th, 2011. Is that a fair statement?
MR. RUMANEK: Objection to form.
THE WITNESS: Yes.
BY MR. THOMPSON:
Q Now, Doctor, in looking through the records in 2005 do we find within the medical records, any indication by any medical professional that the

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problems that Miss Bailey suffered from were caused by a defect in the TVT mesh that she had been implanted with?
A Not to my knowledge, no.
Q In fact, as we sit here today in 2016, we've spent now going on four and a half hours in which your opinion is that there is no defect in the TVT; isn't that right?
A That's correct.
Q In 2005 had Miss Bailey sought information relating to the defect or whether the TVT was defective or had any kind of problems, she could not have found that information, could she?
MR. RUMANEK: Objection to form.
THE WITNESS: If you are asking if she could find out the risks associated with the TVT, she could.
BY MR. THOMPSON:
Q I'm talking about if the suggestion that the risks presented by the TVT were a result of some defective design or defective material of the TVT device.
A I think I'm confused about what you are asking.

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Q My question is, if Miss Adams -- I'm sorry. Now I'm confused. If Miss Bailey had gone looking in 2005 and said, oh, gosh, what's happened to me; I need to investigate and find out more about this, she could not have found from any source, a suggestion that the TVT device itself was defective --
MR. RUMANEK: Objection to form.
BY MR. THOMPSON:
Q -- would she?
A No, because it's not true.
Q I'm sorry.
A There was no evidence to --
MR. RUMANEK: Just let me just object. Objection to the extent you're asking her to testify as to what Miss Bailey could or could not have found in 2005. She can testify as to what she knows, but not what Miss Bailey could or could not have found.
MR. THOMPSON: All right.
BY MR. THOMPSON:
Q In 2005 upon your graduation from med school if you had gone looking, could you have found information that would have provided you with proof that would put you on notice that the TVT was

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defective?
MR. RUMANEK: Objection to the form of the question.
THE WITNESS: No.
BY MR. THOMPSON:
Q Now, there is no doubt that the -- not erosion but exposure that Miss Bailey suffered, was caused physically by the mesh; isn't that right?
MR. RUMANEK: Objection to form.
THE WITNESS: It was associated with the mesh, yes.
BY MR. THOMPSON:
Q Now, Miss Bailey also complains of various things: Pelvic pain, I think, and she complains of dyspareunia. Doctor, is it your opinion that the mesh substantially contributed to those complaints?
MR. RUMANEK: Objection to form.
THE WITNESS: I think that's unlikely.
BY MR. THOMPSON:
Q Now, as you go through and look at, say, for example, the dyspareunia complaint of Miss Bailey, how do you approach her complaint in terms of diagnosing it and in terms of ascertaining the source

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of her complaint? How do you approach that as an expert?

A You have to consider the patient's symptoms, what they are describing, the timing of their description, their age and other potential risk factors. She had other surgeries, including collagen injections, which can be associated with tenderness. The risk of dyspareunia with the TVT is very low, one percent or less, and she -- I'm not -- if I remember correctly, her complaints of dyspareunia are more recent than -- you know, she had this done ten years ago.

But now we were alluding to the fact that vaginal atrophy would not have been an issue at the time of her implantation most likely but certainly could be an issue now, and I think that her dyspareunia is a current complaint, so in my mind it's more likely to be things that have a higher incidence of dyspareunia associated with them, like vaginal atrophy, for instance, rather than a TVT who -- a TVT that has a very low risk of causing dyspareunia, and in particular, since most of the vaginal portion of the TVT has been excised.

Q Now, have you ever conducted a survey or

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a study with regard to the remnant sections of a TVT? I mean, after the -- sort of the central portion has been revised or removed and there are these remaining two arms, do those two arms participate in pelvic pain or dyspareunia?

A They should not, no.

Q Now, what you told me about dyspareunia is that you've looked at her record. Is there any process by which you rule out alternative causes? Have you sort of systematically gone and sort of made a differential and ruled out alternative causes of her dyspareunia?

A It's hard to do that with such a scarce record.

Q I see.

A But yes, I have attempted to do that with what I have been -- am given, and it appears to me from the record that she had some tenderness at the site of the vaginal mesh erosion or she was complaining of dyspareunia when she had a mesh erosion, which is not uncommon, and now that that has been resolved, it would be likely that if dyspareunia was related to that, that that would be resolved as well.

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Certainly she could have, you know, vaginal atrophy. She had collagen injections that can sometimes cause pelvic pain as well, so there are other potential risks that could be contributing to dyspareunia if it is present currently, but it would be unlikely that if her dyspareunia was due to the mesh erosion or due to the sling, that after excising the vaginal portion of the sling, that she would still have dyspareunia due to the sling.

Q I guess I'm at a little bit of a disconnect here. What I am hearing is that you go in and you excise the portion and then it's gone, and so what is -- there is nothing there to hurt. Is that what I am hearing?

A Yes. In the vaginal compartment, yes.

Q But here is my question. I mean, the TVT was implanted for four years. The whole theory of a TVT device is that there will be ingrowth of some form of fibrous material, some scar or, you know, vascularity in her nerves; giant cells. All of those things, the whole design of this product, is to allow ingrowth; isn't that right?

MR. RUMANEK: Object to the characterizations within the question.

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THE WITNESS: Tissue ingrowth in terms of fibroblast and collagen, yes.

BY MR. THOMPSON:

Q So when you excise the mesh, it's not like you're slipping a little card out of your camera? You actually are cutting away material, which includes living material; isn't that right?

A I'm not sure what you mean by living material.

Q I mean, the stuff that grows in through the inflammatory process is alive, isn't it?

MR. RUMANEK: Object to the characterization of the question.

THE WITNESS: I'm not sure what you mean by that.

BY MR. THOMPSON:

Q I mean, these are living cells that grow into the mesh material?

A There is tissue ingrowth, yes.

Q So when you cut out the mesh, you're cutting out that tissue with it? I mean, that's just how you resect it; isn't that right?

A Not exactly. I mean, you dissect the sling out, so you do some separation of the sling from

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the surrounding tissue and then remove the sling. There should -- there probably is some tissue that gets removed with the sling.

Q I guess my question is, why would it be not just as likely that the removal of the sling would result in some inflammatory response that could cause either a continuing pain or even enhanced pain as a result of that removal operation? Wouldn't that have to be on your differential?

MR. RUMANEK: Objection to form. That's different than what you were asking.

THE WITNESS: That's a possibility. It's just unlikely.

BY MR. THOMPSON:

Q I see.

A That's not what we see most often in clinical practice, but that is possible.

Q I see. I see. With regard to Miss Bailey to -- well, let me strike that. Dr. Adam in his operative report, does he make reference to encountering bulking agents?

A He would not. The bulking agents are upon the urethra itself.

Q I see. Okay. So when he noted that the

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urethra was not eroded, then he would not have investigated that further; is that right?

MR. RUMANEK: Objection to form.

THE WITNESS: He -- he may have seen bulking agents with a cystoscopy, but he would not have noted but -- the material with dissection.

BY MR. THOMPSON:

Q I see. Didn't he perform a cystoscopy?

A He did.

Q Let's find that record because that just jumped into my mind that I don't know the answer to that.

MR. RUMANEK: While you-all are looking for that, can we take a couple-of-minute break?

MR. THOMPSON: Certainly.

(A recess was taken.)

BY MR. THOMPSON:

Q And are you ready? Doctor, what does the report say at cystoscopy about the bulking agents?

A It doesn't mention them.

Q But you say he would have seen them on a cystoscopy?

A He might have seen them on cystoscopy.

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If he did see them, that's where he would have seen them: On cystoscopy, not vaginal dissection.

Q But we can say that the record has no observation of bulking agents?

A It -- it talks about there being a shelf --

Q Yes.

A -- that there was -- it was difficult to insert the cystoscope, but he does not say that that was due to the urethral bulking agents.

Q I've gotten bogged down with some interest. Let me go through these additional opinions, and I'm going to try to be -- I know you will not believe this, but I'm going to try to be disciplined about it. Okay? Let's go to Number 4, your opinion Number 4 at page 28.

A Yes.

Q I think I -- well, let me ask it this way. In your report you say, "I do not have any records documenting Miss Bailey's urinary symptoms prior to the placement of her TVT sling," and the question that I have is that given the absence of any records prior to the placement of the TVT sling and given the state of her records, can you say to

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reasonable medical certainty that she still has an overactive bladder syndrome, or is this simply a possibility?

MR. RUMANEK: Objection to form.

THE WITNESS: I can say with --

MR. RUMANEK: Are you talking about prior to the TVT sling placement, or are you talking about --

MR. THOMPSON: No. I'm talking about her opinion Number 4.

BY MR. THOMPSON:

Q Miss Bailey may still have overactive bladder symptoms?

A Yes. I can say that with a reasonable degree of medical certainty.

Q And your basis for that is what?

A Her sensation of urgency, the sensation of a full bladder when her bladder is not full, and improvement in her incontinence with the treatment of Ditropan.

Q Let's go to Number 5. Dr. Adam noted vaginal scarring, which is a known risk of any surgical procedure to treat stress incontinence. All right. I guess your opinion is that the scarring he

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noted was simply a known risk of any surgical procedure?
A Yes.
Q I think that's self-explanatory.
"Miss Bailey's dyspareunia is most likely not caused by her TVT, as she described that her dyspareunia was the same in severity and location as prior to Dr. Adam's revision procedure."
Okay. Now, Doctor, we've actually kind of talked about whether or not the revision would cure and, in essence, deaden any kind of pain point that Miss Bailey would have suffered from. We've already discussed that enough, but you make a point that she should have been describing her dyspareunia as tenderness at the mouth of the vagina or as penetration occurred and not deep.
Am I getting that right?
MR. RUMANEK: Objection to form --
THE WITNESS: Yes.
MR. RUMANEK: -- to the extent it mischaracterizes her report.
BY MR. THOMPSON:
Q Well, I guess that's -- my question is, you think that some of her reporting is inconsistent

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with dyspareunia caused by a TVT device; is that right?
A That's correct.
Q And that's because you would expect the discomfort to be at the opening of the vagina as opposed to deep; is that right?
A That's correct.
Q Now, you actually wrote on this, didn't you? Where was that? It's somewhere. We have a -- well, I'm sure that I've read this somewhere. Here we go.
MR. THOMPSON: Let's mark that.
(Plaintiffs' Exhibit Number P-3 was marked for identification.)
BY MR. THOMPSON:
Q This is an article that you wrote. You're the primary author. "Does the Prolift System Cause Dyspareunia?" We've marked this as Plaintiffs' Exhibit 3, and I will say this. We're talking about TVTs and not Prolift. I'm slow, but even I figured that out. But here is my question to you, and I'm going to -- since you're familiar with this paper, I am going to send you directly to table Number 2.
Now, with regard to the Prolift, at

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least, it looks like there are some ladies who responded to your survey and said, oh, shallow penetration only. Nobody reported deep penetration only. But then the others reported some shallow, some deep, and then some what they describe as total.
Now, is the Prolift unique and different in presentation of dyspareunia from the TVT?
A Oh, absolutely.
Q Oh, okay. So the first thing you would tell me is that this has nothing to do with the TVT; is that right?
A That's correct.
Q Understanding that, it's interesting to know your methodology, that you have a shallow, a deep, a mixed, and a total. Would you say that that gridding is valid for characterizing all sorts of dyspareunia?
MR. RUMANEK: Objection to form.
THE WITNESS: Yes. But the Prolift is total vaginal mesh.
BY MR. THOMPSON:
Q Right.
A So the Prolift is located deeply; it's located shallowly. It's in those physical positions,

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and so it's more common to see various presentations for dyspareunia, in particular in association with a mesh that's in those various locations, whereas the sling is located just distally.
Q Has anybody ever done a study like you did on the Prolift? Has anybody ever done one for TVT?
A Not that I'm aware of.
Q Well, now, one of the occasional and, in your view, very occasional, but one of the occasional adverse reactions is dyspareunia; isn't that right?
A That's been reported, yes.
Q But you're telling me that nobody actually knows the answer to deep, shallow, mixed, total, all that stuff?
MR. RUMANEK: Objection to the form of the question to the extent --
BY MR. THOMPSON:
Q I mean, nobody's studied it?
MR. RUMANEK: That's a very difficult question. Can you repeat your question just so it's clear on the record?
BY MR. THOMPSON:
Q Nobody has studied that differential

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effect of dyspareunia on TVTs, have they?
A Not in this way, no.
Q So when you are relating your opinion, you're relating your anecdotal clinical experience; isn't that right?
MR. RUMANEK: Objection to the form to the extent it mischaracterizes the testimony. She talked about anatomical as well as her own clinical.
BY MR. THOMPSON:
Q Are you going to adopt Eric's answer, or should I just ask another question?
MR. RUMANEK: Well, I'm sorry. You're mischaracterizing the testimony.
MR. THOMPSON: So that's your objection? Let me just withdraw the question because it sounds like it was a bad question.
BY MR. THOMPSON:
Q The basis for your opinion that Miss Bailey's dyspareunia is unrelated to her TVT, is your clinical experience; is that right?
A That and the fact that mid-urethral slings have a very low incidence of dyspareunia. When I have seen dyspareunia in patients that have

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mid-urethral slings, they have been in the area and location of the sling, which is distal in the vagina.
Q And so you have related that back also to your clinical experience; correct?
A That's correct.
Q Have you ever, like, gone to the database and checked on your 800 people to find out if any of them have ever complained of dyspareunia?
A We don't have a database.
Q I mean, could you track down the 800 people that you've installed TVTs in?
A I could look at their electronic medical records to see what visits they've had and whether or not they've complained, follow-up visits, about painful intercourse if they've, you know, followed up at Kaiser.
Q And that would require you to go and formulate a plan that would pass the IRB. Any effort to pull up individual patients that you were not actively treating, invokes a HIPAA; is that right?
A That's right. But the unique thing about my situation is that Kaiser patients are required to see Kaiser doctors, so if there were a patient who had painful intercourse after having a sling that I

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placed, they would almost be required to see me before going outside of the organization, so it would be likely that I would be aware of it or have some Gestalt.
Q I see. And then seven, "It is unlikely Miss Bailey will suffer any further complications from her TVT." Your first sentence is, "It would be speculative to suggest that Miss Bailey will suffer any further complications"; is that correct?
A That's correct.
Q And it's also speculative to suggest that she will not suffer further complications; isn't that right?
MR. RUMANEK: Objection to form.
THE WITNESS: No. We have a significant amount of evidence and data that supports the fact that the incidence of complications with mid-urethral slings, including the TVT, is very low, and that certainly includes TVTs that have been revised or excised as well, partially excised.
BY MR. THOMPSON:
Q I guess my point would be that you really have no idea about Mrs. Bailey's prognosis as we sit

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here today, do you?
MR. RUMANEK: Objection to form of the question to the extent it mischaracterizes her testimony and what is contained in the report.
THE WITNESS: No. Actually, I do. We have -- you know, 3 million women have been implanted with mid-urethral slings, and we have great -- large randomized control trials, the Cochrane Review that includes 12,000 women that gives us an indication and actual incidence rates of complications with mid-urethral slings.
BY MR. THOMPSON:
Q Well, you know, this message from the president that I was handed this morning, it has an interesting line in it, and I'm going to read it to you. It says, "The mid-urethral sling is the most studied procedure for SUI medical literature. However, the majority of that data is from outside the United States, and there remains gaps in the literature around longer-term outcomes.
The board has approved the development of an SUI surgery registry to track physician-reported process and outcome measures as well as

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patient-reported outcomes. It's our hope that this US-based registry will be used by AUGS members as a way to track their outcomes, which will contribute to the medical literature on the value of all SUI surgical options."

Did you read that when it came in?

A I did.

Q So, I mean, are you in agreement that most of the literature or most of the data is from outside the United States?

A I'm not aware of that. I don't have any evidence necessarily to refute that. I understand that there are 81 randomized control trials. Where they come from, I don't know, but we do have -- you know, they're summarizing the data, including all mid-urethral slings. The TVT is somewhat unique in that it was the first that was developed, so we do have long-term data on the TVT.

Q Well, you're referring to Dr. Nielsen and his 17-year study?

A Dr. Nielsen's study is one, yes.

Q Now, he's in Finland, isn't he?

A I don't know where Dr. Nielsen is.

Q Here is my question.

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MR. THOMPSON: We probably ought to go ahead and just mark these since they're in the case.

(Discussion ensued off the record.)

BY MR. THOMPSON:

Q We are just going to include those. We don't need to talk about that anymore.

(Plaintiffs' Exhibits Numbers P-4 and P-5 were marked for identification.)

BY MR. THOMPSON:

Q Has your discussion with your patients with regard to risks and benefits and potential complications, has it changed since you've started at Kaiser in 2008 to the present? Do you do more consulting or talking with your patients than you did in 2008?

A Yes.

Q And why is that?

A Because patients are very hesitant now. They always ask the question, well, isn't that, that mesh that they talk about on TV? So I have to explain the FDA public health notification. I have to discuss the AUGS position statement. There is more that has to be explained to give them some reassurance that

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it's a safe and effective procedure, so yes.

Q All of these 81 studies that you are talking about, and let's look at Dr. Nielsen with his 17-year study where he's followed these ladies in Finland. All of these studies are performed by folks like you, aren't they?

MR. RUMANEK: Objection to form.

BY MR. THOMPSON:

Q University trained, intensive fellowship, fellow positions, maybe even academic positions. All of these people fall into this category of highly trained, highly competent surgeons, don't you agree?

MR. RUMANEK: Objection to form.

THE WITNESS: Well, usually the principal investigator is not the only surgeon that's included in the -- the randomized control trials that they're sort of overseeing, so typically they will involve surgeons in the community as well, so not everyone is as well trained as, you know, possibly the principal investigator is.

BY MR. THOMPSON:

Q Well, you know where I'm going to now, and that is, if these safety studies are being run by

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either academic settings or settings with tertiary, highly specialized, highly competent folks, how do you gather the data on women who are going to storefront stand-alone OBs who have gone and taken a cadaver course and are implanting? How do you capture the data on those people, on those ladies?

MR. RUMANEK: Object to the form of the question; characterization.

THE WITNESS: In most randomized control trials they do include surgeons in the community. It's not just expert surgeons that are included in randomized control trials. It would be very difficult to do that on -- you know, with 12,000 patients, so the larger the number of patients that are included, the more representative the research is in terms of how that exposure --

BY MR. THOMPSON:

Q Yes.

A -- is experienced in the community, which is why Cochrane Reviews are so important or meta-analyses like what we talked about before with Schimpf: Because they include multiple studies under multiple conditions --

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Q Yes.
A -- not just the top university centers, but multiple practicing physicians, and we can summarize that data and get a better -- or a more reliable picture of how that surgery or exposure or whatever it is that you are looking at, is experienced by the general population.
Q Yeah.
A We can't know how it's experienced by every single surgeon and every single patient, but the goal is to try to approximate the experience as best we can, and the best way to do that is with large randomized control trials and large meta-analyses.
Q Well, I understand that, but let's go back to Kaiser. I mean, you have 2 million folks out in California. You have 260,000 folks here. Isn't the best way nowadays would be to do some epidemiological study and see the impact of this on the population, not as a prospective clinical trial but as a registry of the outcomes?
MR. RUMANEK: Objection to form.
BY MR. THOMPSON:
Q I mean, isn't that a better way to look at it?

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A No because you can't assess incidence with registries. You have to be able to evaluate things prospectively and randomly to assess for -- or to account for bias. It has to be systematic or you expose yourself to bias.
Q And if I look at the report -- I think I've now put it into evidence, but if I look at the Schmidt -- is that right?
MR. RUMANEK: Schimpf.
THE WITNESS: Schimpf. Sorry.
BY MR. THOMPSON:
Q If I look at that, if I go down and I run my finger down the end number for the number of patients in all of those many reports, usually those trials are very small numbers; is that right?
A Right. That's the purpose of meta-analyses is to be able to combine the numbers to give you greater reliability of the outcome data.
Q Well, is it your view as an expert that the combining many, many low-number studies increases the power of the meta study?
MR. RUMANEK: Objection to form.
THE WITNESS: Yes.
MR. THOMPSON: Eric, I'm going to stop asking questions. I think the rule is that I should say I reserve.
MR. RUMANEK: I'm going to look at my notes. I don't think I'm going to have any questions. Give me a couple of minutes.
(Discussion ensued off the record.)
MR. RUMANEK: I can go on and say I don't have any questions. I have no questions for witness.
MR. THOMPSON: All right. Thank you very much.
(Deposition concluded at 2:08 p.m.)
(Pursuant to Rule 30(e) of the Federal Rules of Civil Procedure, signature of the witness has been reserved.)

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C E R T I F I C A T E

STATE OF GEORGIA)
COUNTY OF GWINNETT)

I hereby certify that the foregoing transcript was taken down, as stated in the caption, and the proceedings were reduced to typewriting under my direction and control.
I further certify that the transcript is a true and correct record of the evidence given at the said proceedings.
I further certify that I am neither a relative or employee or attorney or counsel to any of the parties, nor financially or otherwise interested in this matter.
This the 28th day of June, 2016.

THOMAS R. BREZINA, B-2035

ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
JOYE LOWMAN, M.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.
My commission expires:_____

_____
Notary Public

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